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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,681	11/08/2001	David G. Barkalow	112703-198	4991
29156	7590	03/31/2004	EXAMINER	
BELL, BOYD & LLOYD LLC			SHEIKH, HUMERA N	
P. O. BOX 1135			ART UNIT	
CHICAGO, IL 60690-1135			PAPER NUMBER	

1615

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,681	BARKALOW ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 25-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Remarks/Response, both filed 12/29/03 is acknowledged.

Claims 16-19 and 25-43 are pending. Claims 20-24 have been cancelled as requested. No further amendments to the claims have been made. Claims 16-19 and 25-43 remain rejected.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19, 25-39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers (US Pat. No. 5,433,960).

Meyers discloses an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%) wherein the edible film composition also comprises at least one or more active agents located in the

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edible film, which include *dental agents* (i.e., plaque pH buffers/inhibitors, minerals, antimicrobial agents, microbial inhibitors, phosphates); flavor enhancers, sweeteners, softeners and antioxidants (see reference column 3, line 15 thru col. 14, line 18); (col. 6, line 20 thru col. 11, line 55) and claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960) in view of Zerbe *et al.* (US Pat. No. 5,948,430).

As discussed above, Meyers teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%).

Meyers teaches that suitable water-soluble film forming agents include, asides from the celluloses and starches, edible polymers, edible plastics, low calorie bulking agents, vegetable gums, such as guar gum, locust bean gum, carrageenan gum, alginates, etc. The preferred water-soluble film forming agents are cellulose derivatives, which include ethyl cellulose, methyl cellulose, hydroxypropyl cellulose and sodium

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hydroxymethyl cellulose. The film-forming agent can be used in amounts of about 5% to about 25% (col. 6, lines 20-50). The ranges of film-forming agents taught by Meyers are overlapping ranges (instant range – ~10 - ~90%).

Bulk fillers, such as calcium carbonate, magnesium carbonate, talc and dicalcium phosphate are disclosed in amounts of between 5-95% at col. 9, lines 14-22.

According to Meyers, plasticizers are added to improve the flexibility of the film. Plasticizers mentioned herein include glycerin, polyethylene glycol (PEG), polyols and hydrogenated starch hydrolysates. The plasticizer may be contained in amounts of about 0.5-15% (instant range - <20%) (col. 8, line 7 thru col. 10, line 30).

Additionally, at least one or more active agents are included in the edible film forming composition, as delineated above.

Meyers teaches the use of various acids at col. 8, lines 5-11. Meyers is deficient only in the sense that he does not teach an acid from the selective group of claim 40.

Zerbe *et al.* teach a water-soluble film composition for oral administration comprising film-forming agents, fillers, plasticizers and flavor-enhancing acids, wherein suitable acids include tartaric acid and citric acid (col. 2, line 1 thru col. 3, line 40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Zerbe within Meyers, because Zerbe explicitly teaches a water-soluble film forming composition comprising cosmetically active agents such as flavor-enhancing acids (i.e., tartaric, citric) to impart an enhancement of flavor to the composition and similarly, Meyers teaches an edible

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water-soluble film forming composition comprising active agents that include flavor enhancers and discloses various acids (i.e., stearic, lauric, palmitic, arachidic, oleic, linoleic and eladic acids). The expected result would be an edible film-forming composition capable of imparting enhancement of flavors and freshness of the mouth.

Response to Arguments

Applicant's arguments filed 12/29/03 have been fully considered but they are not persuasive.

Firstly, the Applicant argues regarding the 35 U.S.C. §102(b) rejection of claims 16-19, 25-39 and 41-43 over Meyers (US 5,433,960) stating, "The claimed invention provides a **pullulan-free edible film** composition. Meyers discloses an edible film that coats a chewing gum. This edible film can include pullulan (col. 8, line 6). Meyers teaches away and does not anticipate the invention. The claimed invention requires two specific film-forming agents, cellulose and starch. Meyers fails to disclose the use of these two specific film forming agents but rather discloses a litany of different film forming agents stating that these agents can be used in combination. Never does Meyers disclose specifically the use of cellulose and starch as the film forming agents. Nowhere has the Patent Office referred to where bulk filler and plasticizing agent are present in Meyers. Applicants request specific identification in Meyers where the components of an edible film having the bulk filling agent and plasticizing agent are met."

These arguments have been fully considered, but were not found to be persuasive. Applicant's argument that instant claims recite "pullulan-free edible film" composition, whereas Meyers edible film *can* include pullulan is not persuasive since the pullulan disclosed by Meyers is deemed an optional component. Nowhere in the

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Meyers reference does it state that pullulan *must be* included in the edible film. Moreover, as that Applicant admits in the arguments, 'Meyers edible film *can* include pullulan', which can be interpreted as pullulan being an entirely optional component in the formulation. More specifically, Meyers at cols. bridging 7 & 8, Meyers states "a great number of ingredients are envisioned for use as the edible film. These include.....pullulan". Therefore one of ordinary skill in the art would be capable of including any of the ingredients listed and excluding any based on the desired or intended purpose. Even further, the Examiner notes that Claims 1-29 of Meyers patent do not include any mention of pullulan in the edible film formulation.

The Applicants' arguments that 'Meyers does not disclose specifically the use of cellulose and starch as the film forming agents but rather discloses a litany of different film forming agents' is also not persuasive. Meyers at cols. 6, lines 23-38 discloses that suitable water-soluble film forming agents include cellulose derivatives, modified starches, maltodextrin, etc. The incorporation of at least one ingredient chosen from various celluloses and starches as suitable film-forming agents is also disclosed in Claim 1 of the '960 patent.

The Applicant also inquired as to the specific location as to where bulk fillers and plasticizing agents are mentioned. Meyers at column 9, lines 14-22 discloses the use of bulk fillers, such as calcium carbonate, magnesium carbonate, talc, dicalcium phosphate and the like in amounts of between 5-95%. Calcium carbonate and polyethylene glycol (PEG) are also disclosed at col. 8, lines 16 and 9, respectively. Plasticizers (or softeners) are disclosed at col. 9, lines 24-35 and include glycerin,

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polyethylene glycol (PEG), polyols, hydrogenated starch hydrolysates, corn syrup, etc. in amounts of about 0.5-15%.

Lastly, the Applicant argues regarding the rejection of claim 40 over Meyers ('960) in view of Zerbe (US 5,948,430) stating, "Zerbe does not remedy the deficiencies of Meyers set forth above."

These arguments have been fully considered, but were not found to be persuasive. The teachings of Meyers and Zerbe have been delineated above. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Meyers teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrins, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%). Meyers was lacking only in terms of the selective acid of claim 40. Zerbe clearly remedies the only deficiency of Meyers and was relied upon solely for the teaching of a water-soluble film composition that comprises suitable acids that include tartaric acid and citric acid as instantly claimed (see col. 3, line 37).

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For the foregoing reasons, the instant invention is rendered unpatentable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571)

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272-0604. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

March 26, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600